REMARKS

The amendments to the specification and claims are highlighted in an Appendix in which added material is underlined and deleted material is enclosed in square brackets.

1. Drawings

The Office Action objects to the drawings as not showing the drug storage compartment. Figs. 3 and 4 have accordingly been amended to show the drug storage compartment interfaced with part of the face mask system as described in the paragraph at p. 6, ll. 30 – 32, and that paragraph has been amended to recite reference sign 225 as referring to the drug storage compartment. No new matter has been added by such amendment.

A copy of the new drawings is attached with the changes highlighted in red.

2. Specification

The Office Action objects to the specification as failing to provide an adequate written description how the intrathoracic pressure is lowered by the valve system and how a patient can breathe through the valve system while respiratory gas flow is inhibited. This objection is respectfully traversed.

In addition to the description of the mechanism and operation of the valve system provided explicitly in the specification, details of the valve system are provided in a number of patents and applications incorporated by reference, including U.S. Pat. Nos. 5,551,420; 5,692,498; 6,062,219; 5,730,122; 6,155,257; 6,234,916; and 6,224,562; and U.S. Pat. Appl. No. 09/966,945. It is believed that the current specification, together with

the supplementary description of the valve system provided in these references, provides the support required. Applicants therefore request that the objection to the specification be withdrawn. *See* MPEP 2163.07(b) ("The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed.")

The paragraph at p. 3, ll. 13 – 23 has been amended to update the reference to U.S. Pat. Appl. No. 09/966,945 with it serial number.

3. Claim Rejections

Claims 1 – 13 stand rejected under 35 U.S.C. §112, first paragraph as containing subject matter not sufficiently described in the specification. These rejections are respectfully traversed. In particular, as noted above, it is believed that the current specification, together with the supplementary description of the valve system provided in material incorporated by reference provides full support for the claims, including the specific issues identified in the Office Action.

The Office Action additionally questions whether a limitation recited in Claim 1 requires lowering of the negative or positive intrathoracic pressure. It is not believed to be necessary to restrict the limitation in the manner suggested. In particular, the claim already includes a limitation that the valve system is configured "such that the intrathoracic pressure is less than atmospheric pressure," thereby providing a specific reference for defining the change required by the "lowering" limitation. Specifically, the intrathoracic pressure is lowered to less than atmospheric pressure by the valve system.

Claims 6 and 11 stand rejected under 35 U.S.C. §112, first paragraph as failing to be supported by a teaching that the recited pressure range is "exceeded." These rejections are respectfully traversed. Claim 6 has been amended to recite that it is a magnitude of the threshold negative intrathoracic pressure that is to be exceeded. Applicant notes the specific teaching in the specification of a configuration for the valve

system that prevents respiratory gases from flowing into the lungs until this magnitude is exceeded:

> During the recovery or decompression phase of CPR where the patient's chest is actively lifted or allowed to expand, valve system 200 *prevents respiratory gases from flowing into the lungs until a threshold of negative intrathoracic pressure level is exceeded.* When this pressure level is exceeded, check valve 224 is pulled downward as springs 224a are compressed to permit respiratory gases to flow through openings 226 and to the patient's lungs by initially passing through tube 208 and duck bill valve 212. *Valve 224 may be set to open when the negative intrathoracic pressure is in the range from about 0 cm H_2O to about –40 cm H_2O,* and more preferably from about –5 cm H_2O to about –30 cm H_2O. Hence, the magnitude and duration of negative intrathoracic pressure may be enhanced during decompression of the patient's chest by use of valve system 200. (Application, p. 6, ll. 17 – 26, emphasis added).

Similarly, with respect to Claim 11, the specification provides the following teaching:

> The valve system may optionally have an attached valve to create a range of positive end expiration pressures (PEEP) that typically occurs during compression of the patient's chest or when the patient exhales. This valve may be set to open when the positive intrathoracic pressure is in the range from about 0 cm H_2O to about 20 cm H_2O. (Application, p. 2, ll. 14 – 18).

Adapting the valve system in this way is also disclosed, for example, in U.S. Pat. 6,062,219 at Col. 8, l. 60 – Col. 9, l. 6, which has been incorporated by reference (Application, p. 3, ll. 18 – 23).

Claims 1 – 13 stand rejected under 35 U.S.C. §112, second paragraph as indefinite. These rejections are traversed in part and overcome in part.

Claim 1 stands rejected for its use of the phrase "some time." As used in the claim, the phrase forms part of a limitation requiring that the valve system be "configured to prevent or impede respiratory gases from flowing into the lungs *for at least some time*" (emphasis added). As such, it distinguishes from a circumstance where the flow is impeded instantaneously and is therefore believed to have a well-defined meaning under §112.

Claim 4 stands rejected for its use of the term "and/or." The claim has been amended to use the term "or" instead, with the intention that it be construed

inclusively, i.e. that the phrase "respiratory or abdominal" mean respiratory, abdominal, or respiratory and abdominal.

It is believed that the rejection of Claim 6 is obviated by the amendment that requires the range of 0 – 40 cm H_2O to be a range for a magnitude of the threshold negative intrathoracic pressure.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

The amendments to the specification and claims are highlighted below by underlining added material and enclosing deleted material in square brackets.

1. Specification

The paragraph at p. 3, ll. 13 – 23 has been amended as follows:

The invention may be implemented by enhancing the negative intrathoracic pressure within the patient's chest to in turn enhance blood flow to the thorax to facilitate circulation of the drug throughout the blood stream and to the vital organs. This may be accomplished by preventing or impeding the flow of respiratory gases to the lungs under a variety of conditions, such as when performing CPR, when causing the respiratory or abdominal muscles to contract, when actively breathing, and the like. To prevent or impede respiratory gases from flowing to the lungs, a variety of impeding or preventing mechanisms may be used, including those described in US Patent Nos. 5,551,420; 5,692,498; 6,062,219; 5,730,122; 6,155,257; 6,234,916 and 6,224,562 and US Patent Application No. 09/966,945 [_____], filed on the same date as the present application **[(attorney docket no. 16354-004400)]**, the complete disclosures of which are herein incorporated by reference.

The paragraph at p. 6, ll. 30 – 32 has been amended as follows:

Conveniently, a drug storage compartment 225 may be interfaced with or part of a face mask system that includes the valve system. In this way, an appropriate drug may be rapidly accessed when needed.

2. Claims

Claims 4 and 6 have been amended:

1. (As Filed) A method for administering a drug to a patient, the method comprising:

coupling a valve system to the patient's airway, wherein the valve system is configured to prevent or impede respiratory gases from flowing into the lungs for at least some time such that the intrathoracic pressure is less than atmospheric pressure;

introducing a drug into the patient;

lowering the intrathoracic pressure using the valve system to cause blood to flow into the thorax and thereby increasing vital organ perfusion to enhance the circulation of the drug.

2. (As Filed) A method as in claim 1, wherein the patient is under cardiac arrest, and wherein the intrathoracic pressure is reduced during a decompression phase of CPR when performing CPR and also preventing or inhibiting respiratory gas flow into the lungs with the valve system.

3. (As Filed) A method as in claim 1, wherein the intrathoracic pressure is reduced by breathing in while preventing or inhibiting respiratory gas flow to the lungs with the valve system.

4. (Amended) A method as in claim 1, wherein the intrathoracic pressure is reduced by stimulating the phrenic nerve to cause the respiratory **[and/]**or abdominal muscles to contract while preventing or inhibiting respiratory gas flow to the lungs with the valve system.

5. (As Filed) A method as in claim 1, wherein the intrathoracic pressure is reduced by squeezing the chest and relaxing the chest with a chest caress while preventing or inhibiting airflow to the lungs with the valve system.

6. (Amended) A method as in claim 1, wherein the valve system is configured to prevent respiratory gases from entering the lungs until a magnitude of a threshold negative intrathoracic pressure in the range from about 0 cm H_2O to about 40 cm H_2O is exceeded.

7. (As Filed) A method as in claim 1, wherein the drug is administered by a process selected from a group consisting of intravenously, through the patient's bone, through the patient's airway, orally, nasally, endobrochially, rectally, and transdermally.

8. (As Filed) A method as in claim 1, wherein the drug is administered through a facial mask or the valve system.

9. (As Filed) A method as in claim 1, wherein the drugs are selected from a group consisting of glucose, sodium bicarbonate, oxygen, steroids, vasopressor drugs, anti-arrhythmic drugs, anti-seizure, anti-asthma, anesthetics, and cooling solutions to cool the brain during cardiac arrest.

10. (As Filed) A method as in claim 1, wherein the valve system is configured to permit respiratory gases to exit the patient's lungs, and further comprising forcing respiratory gases from the lungs and out the valve system.

11. (As Filed) A method as in claim 1, wherein the valve system is configured to prevent respiratory gases from exiting the patient's lungs until a positive end expiratory pressure in the range from about 0 cm H_2O to about 20 cm H_2O is exceeded.

12. (As Filed) A method as in claim 1, wherein the valve system is coupled to a facial mask that is placed over the mouth and nose, and further comprising removing the drug from a drug storage compartment of the facial mask.

13. (As Filed) A method as in claim 1, wherein the valve system is coupled to an inhalation device that includes the drug, and further comprising inhaling from the inhalation device to administer the drug.